NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 6. ECONOMIC SECURITY

CHAPTER 3. DEPARTMENT OF ECONOMIC SECURITY UNEMPLOYMENT INSURANCE

[R05-200]

PREAMBLE

1. Sections Affected Rulemaking Action

R6-3-50155 Amend R6-3-5105 Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 41-1954(A)(1)(A) and 41-1954(A)(3) Implementing statutes: A.R.S. §§ 23-775(1), 23-775(2), and 23-727(D)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 11 A.A.R. 2388, June 24, 2005

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Beth Broeker

Address: Department of Economic Security

P.O. Box 6123, Site Code 837A

Phoenix, AZ 85005

or

Department of Economic Security 1789 W. Jefferson, Site Code 837A

Phoenix, AZ 85007

Telephone: (602) 542-6555 Fax: (602) 542-6000

5. An explanation of the rule, including the agency's reasons for initiating the rule:

The Arizona Department of Economic Security administers the state Unemployment Insurance (UI) program, authorized under Titles II and IX of the Social Security Act, the Federal Unemployment Tax Act, and Arizona Revised Statutes Title 23, Chapter 4.

R6-3-50155 provides guidelines for determining whether an individual who leaves work because of domestic circumstances is eligible for the receipt of unemployment insurance benefits. R6-3-5105 provides general guidelines for determining whether a person who has been discharged from a job will be eligible for benefits.

The proposed amendments to these rules were initiated in response to a petition from an advocacy group. The changes will add specific language to establish that a worker who is a victim of domestic violence is eligible for benefits, if the worker was forced to leave the job or is discharged from the job because of circumstances connected to the domestic violence and beyond the worker's control. The amendments also provide that the employer's unemployment insurance experience rating (tax) account will not be adversely affected since the worker left the job for reasons not attributable to the employer.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

There will be a positive impact on small business and consumers. The proposed changes will ensure that a worker forced to leave the job due to the worker being a victim of domestic violence will be eligible for unemployment insurance benefits. Further, since this type of separation is not attributable to the employer, the employer's experience rating (tax) account will not be adversely affected by the payment of these benefits.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Beth Broeker

Address: Department of Economic Security

P.O. Box 6123, Site Code 837A

Phoenix, AZ 85005

or

Department of Economic Security 1789 W. Jefferson, Site Code 837A

Phoenix, AZ 85007

Telephone: (602) 542-6555 Fax: (602) 542-6000

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department does not plan to conduct an oral proceeding on the proposed rules unless a written request for an oral proceeding is submitted to the person named in item #4 within 30 days after this notice is published. The Department will accept written comments on the proposed rules for 30 days after the date of this publication. All written comments must be submitted to the person named in item #4.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 6. ECONOMIC SECURITY

CHAPTER 3. DEPARTMENT OF ECONOMIC SECURITY UNEMPLOYMENT INSURANCE

ARTICLE 50. VOLUNTARY LEAVING BENEFIT POLICY

Section

R6-3-50155. Domestic circumstances

ARTICLE 51. DISCHARGE BENEFIT POLICY

Section

R6-3-5105. General

ARTICLE 50. VOLUNTARY LEAVING BENEFIT POLICY

R6-3-50155. Domestic circumstances

A. General

- 1. A worker who quits <u>left work</u> because of <u>a</u> domestic <u>obligations</u> <u>obligation</u> involving <u>a</u> legal or moral <u>responsibilities</u> <u>responsibility</u> of such a compelling nature that <u>he the worker eannot could not disregard them it would leave left</u> work for <u>a</u> compelling personal <u>reasons</u> <u>reason</u>.
- 2. However, the mere existence of <u>family such a domestic</u> <u>obligations</u> <u>obligations</u> does not of itself mean that the worker was compelled to leave. If <u>he had</u> <u>the worker</u> had a reasonable alternative to quitting <u>which he that the worker</u> failed to exercise, <u>he</u> the worker <u>will be found to have</u> left voluntarily.
- 3. The availability for work of the individual who leaves for domestic reasons must always be examined.
- **B.** Care of Children. Parents or persons who assume responsibility for the welfare of children not their own are morally and legally obligated to provide care and attention for those children.
 - Leaving A worker who left work to provide care for ehildren a child may be have left:
 - 1. For for a compelling personal reasons reason, depending upon the degree of necessity for the elaimant worker to provide that care. The Department shall consider the following factors when making its determination: These factors should be considered:
 - a. Child's age;
 - b. Health;
 - c. Home and neighborhood surroundings which that might affect the child's safety;
 - d. Availability of child care arrangements: and
 - e. Availability of a leave of absence.
 - 2. With The leaving may be with good cause in connection with the work if:
 - a. The hours of work or place of employment are were changed; or
 - b. The employer, without valid reason, refuses refused a leave of absence.
- C. Home, spouse, or parent in another locality
 - 1. The Department shall consider a A spouse or unemancipated minor who leaves left work to accompany or join the other spouse or parent who has moved to a new locality from which it is impractical to commute shall be considered to have done so left work for a compelling personal reason, not attributable to the employer and not warranting disqualification for benefits, provided that the other spouse or parent moved:
 - a. For a compelling personal reason; or
 - b. For the purpose of establishing To establish a domicile at the new locality for three or more months or longer; or.
 - e. From a locality other than that in which the spouse or unemancipated minor lived and other spouse or parent had no intention, within the foreseeable future, of establishing a domicile at the locality which the spouse or unemancipated minor left.
 - 2. The Department shall consider a A spouse or unemancipated minor who leaves left work to accompany the other spouse or parent who is a member of the armed services and who is transferred to another locality as a result of official orders is considered to have left work for a compelling personal reason, not attributable to the employer and not warranting disqualification for benefits.
 - 3. For the purpose of this Section an "unemancipated minor" is a person who is less than 18 years of age, is single, and who lives in the same household except for temporary absences, e.g., such as school attendance, vacations, or hospitalization, etc.
- **D.** Household duties. An individual who quits A worker who left work because working interferes with household duties leaves left work without good cause in connection with his the work, unless the household duties required of him the worker are so compelling as to leave no reasonable alternative.
- E. Housing
 - 1. When a worker quits <u>left work</u> because of housing problems, it must be determined the <u>Department shall determine</u> if <u>his the worker left leaving was</u> with or without good cause or for a compelling personal reason. Among the The Department shall consider the following factors to be considered are:
 - a. The availability of adequate housing within a reasonable distance to his of the work.
 - b. The cost of housing in relation to wages: and
 - c. Prospects of other work offering a solution to his that eliminate the housing problems problem.
 - 2. A worker leaves left with good cause in connection with his the work if:
 - a. Adequate housing is was promised by an employer and is was not provided; or
 - b. The employer informs informed the worker that housing is was available, but such housing is was so primitive or substandard that it is was a menace to the health of the worker or his the worker's family.
- **F.** Illness or death of others
 - 1. A worker who quits <u>left work</u> because of the death or illness of a member of <u>his the worker's</u> immediate family, or to provide care for a family member would leave left work for a compelling personal reasons reason if:

- a. A leave of absence eannot could not be obtained or would be have been impracticable; and
- b. No other reasonable alternative exists existed.
- 2. A worker <u>leaves left work</u> with good cause in connection with <u>his the</u> work if <u>his the worker's</u> difficulty in caring for <u>the an ill relative is was</u> due to a change in working conditions, or when the employer, without a valid reason, refused to grant a leave of absence for this purpose.
- 3. For the purposes of this Section, the following are members of a worker's immediate family The following shall be considered members of the immediate family in applying this policy:

Father Son
Mother Daughter
Brother Husband
Sister Wife

- a. Spouse
- b. Parent
- c. Child
- d. Sibling
- e. Any other person with a similar relationship to the worker, including foster parent, stepchild, or guardian.

Note: This list may be extended to include other persons whose relationship to the claimant closely resembles the above because of personal circumstance, e.g., foster parents, child raised by a distant relative, etc.

G. Marriage

- 1. When a worker quits <u>left work</u> to <u>be get</u> married or because <u>he the worker</u> has married, the leaving is voluntary <u>and</u> without good cause in connection with the work.
- 2. If the employer terminates terminated the employment because of a company rule which that prohibits continuing employment of both employees when co-workers marry, the separation is a discharge.
- **H.** Domestic violence. Under A.R.S. § 23-771(D), if a worker left work because of domestic violence, as defined in A.R.S. § 13-3601 or § 13-3601.02, the worker has left for a compelling personal reason not attributable to the employer, if:
 - 1. The circumstances required the worker to leave the job and a leave of absence was not available or would have been impractical, or
 - 2. Remaining with the employer would present a threat to the safety of the worker, the worker's family, or co-workers and no other reasonable alternative existed.

ARTICLE 51. DISCHARGE BENEFIT POLICY

R6-3-5105. General

A. Misconduct

- 1. The following constitutes misconduct Misconduct sufficient to disqualify a claimant from receipt of unemployment insurance benefits, pursuant to A.R.S. § 23-775(2); must be
 - a. An an act of wanton or willful disregard of the employer's interest;
 - <u>b.</u> A a deliberate violation of the employer's rules, :
 - c. A a disregard of standards of behavior which that the employer has the right to expect of an employee,; or
 - d. Negligence negligence in such a degree or recurrence as to:
 - i. Manifest manifest culpability, wrongful intent, or evil design, or
 - <u>ii</u>. <u>Show</u> show an intentional and substantial disregard of the employer's interest or of the employee's duties and obligations to the employer.
- 2. A <u>elaimant worker does not</u> need <u>not</u> to have <u>actually acted with intent intended</u> to wrong the employer <u>for the Department to find</u> to result in a finding of misconduct connected with the work. Misconduct may be established if there is:
 - <u>a.</u> <u>Indifference</u> indifference to and neglect of the duties required of the worker by the contract <u>or terms</u> of employment, or
 - <u>A</u> a violation of any material lawful duty required under the employment contract <u>or terms of employment</u>, when <u>the employer expressly such duty is expressed</u> or impliedly <u>set sets</u> forth <u>the duty</u> to the worker and the facts show the worker should have reasonably been able to avoid the situation <u>which that</u> brought about the discharge.
 - 3.i. In determining whether the <u>a</u> worker would be <u>was</u> expected to have avoided the situation which that caused the discharge, consideration should be given the Department shall consider the worker's knowledge of the worker's responsibilities through past experience, explanations, warnings, etc.
 - ii. The <u>Department shall evaluate the</u> materiality of a duty and the materiality of the breach of such duty should be evaluated in the light of by considering what is customary in the type of business in which the claimant was employed.
- **B.** Discharge Separation for a compelling personal reasons reason not attributable to the employer.

- 1. The Department ordinarily restricts the determination of a A separation from work for compelling personal reasons is usually restricted to the circumstances which that have no direct relation to a worker's employment and usually occurs when a claimant worker left quits employment for a cause beyond the claimant's worker's control. However, under the circumstances set forth in (B)(2) below, the Department may make a compelling personal reason determination may be made where when the employer acted to discharge discharged the claimant under subsections (B)(2) and (3).
- The Department may determine A determination that the claimant was discharged for a compelling personal reason when must establish that:
 - a. The employer had no reasonable alternative but to discharge the claimant; and
 - b. One or more of the following circumstances is present:
 - i. The claimant is was discharged because of an absence due to incarceration which that is determined not to be misconduct under R6-3-5115(E)(1).
 - ii. The claimant is was discharged because of a physical or mental condition which that might have endangered the claimant's own safety on the job or the safety of others, for example such as epilepsy, or active tuberculosis, etc.; or
 - iii. The claimant is was discharged because the claimant was unable to properly perform the work due to a physical or mental condition: or
 - iv. The claimant is discharged because the employer has entered into an agreement with another party, other than the claimant, which that would result in a violation by the employer of a federal or state law if the claimant is retained in employment.
- 3. The Department shall determine that a discharge was for a compelling personal reason when a claimant was discharged because of events beyond the claimant's reasonable control as a result of the claimant being a victim of domestic violence. Examples of such events are the claimant receiving unsolicited phone calls, unauthorized visitors, or other types of harassment at the workplace.
- 34. For definitions of "compelling", "personal reasons", and "attributable to the employer", refer to Voluntary Leaving, R6-3-5005(C).

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

[R05-204]

PREAMBLE

<u>1.</u>	Sections Affected	Rulemaking Action
	Article 13	New Article
	R9-25-1301	New Section
	R9-25-1302	New Section
	R9-25-1303	New Section
	R9-25-1304	New Section
	R9-25-1305	New Section
	R9-25-1306	New Section
	R9-25-1307	New Section
	R9-25-1308	New Section
	R9-25-1309	New Section
	R9-25-1310	New Section
	R9-25-1311	New Section
	R9-25-1312	New Section
	R9-25-1313	New Section
	R9-25-1314	New Section
	R9-25-1315	New Section
	Table 1	New Table
	Exhibit I	New Exhibit

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4), (5), and (6)

Implementing statute: A.R.S. § 36-2225(A)(4), (5), and (6)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 10 A.A.R. 3192, August 13, 2004

Notice of Public Meeting on Open Rulemaking Docket: 10 A.A.R. 4854, December 3, 2004

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Vicki Conditt, Trauma and EMS System Development Section Chief

Address: Arizona Department of Health Services

Bureau of Emergency Medical Services

150 N. 18th Ave., Suite 540

Phoenix, AZ 85007

Telephone: (602) 364-3155
Fax: (602) 364-3568
E-mail: condity@azdhs.gov

or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

Office of Administrative Rules 1740 W. Adams St., Suite 202

Phoenix, AZ 85007

Telephone: (602) 542-1264
Fax: (602) 364-1150
E-mail: phillik@azdhs.gov

5. An explanation of the rule, including the agency's reasons for initiating the rule:

A.R.S. § 36-2225 requires the Arizona Department of Health Services (ADHS) to develop and administer a statewide emergency medical services (EMS) and trauma system to implement the Arizona EMS and trauma system plan. As part of developing the statewide EMS and trauma system, ADHS is required by A.R.S. § 36-2225 to adopt rules to establish standards for a trauma center designation and dedesignation process for health care institutions that provide trauma care. A.R.S. § 36-2225 expressly authorizes ADHS to adopt rules allowing for designation based on: (1) a health care institution's verification as a trauma facility by a national verification organization, (2) a determination by a national verification organization that a health care institution meets the state standards established by rule for designation as a trauma center, or (3) a determination by ADHS that a health care institution meets the state standards established by rule for designation as a trauma center. A.R.S. § 36-2225 defines "national verification organization" to mean the American College of Surgeons Committee on Trauma (ACS) or another nationally recognized organization that verifies the ability of health care institutions to provide trauma services at various levels. Currently, ACS is the only national verification organization in existence.

A.R.S. § 36-2222(E)(1) requires the State Trauma Advisory Board (STAB) to make recommendations to ADHS on the initial and long-term processes for the verification and designation of trauma center levels, including the evaluation of trauma center criteria.

A.R.S. §§ 36-2225 and 36-2222(E)(1) were created by Laws 2004, Chapter 292, which became effective on August 25, 2004. A.R.S. § 36-2225 was then amended by Laws 2005, Chapter 52, effective April 11, 2005, to include the language regarding a national verification organization and the permissible bases for designation.

ADHS has been working on the rules for trauma center designation with STAB and the STAB Verification/Designation Work Group (STAB Work Group) since August 2004. Combined, STAB and the STAB Work Group include representation from the Arizona Department of Public Safety, the four EMS Regional Councils, the seven currently self-designated Level I trauma facilities, ACS, the Arizona Fire District Association, the Arizona Hospital and Healthcare Association, Indian Health Services, the American Academy of Emergency Physicians, a statewide rehabilitation facility, urban and rural advanced life support base hospitals that are not trauma centers, the Arizona Ambulance Association, the American Association of Retired Persons, Phoenix Fire Department, a tribal health organization, and Phoenix Children's Hospital.

Notices of Proposed Rulemaking

After obtaining STAB Work Group approval and STAB approval of draft rules for trauma center designation in November 2004, ADHS solicited public comment on the draft rules through mass mailing and mass e-mailing to potentially interested persons, presented information at EMS Regional Council meetings, and held a public meeting on an open rulemaking docket to obtain oral comment. After revising the draft rules as a result of input received and further internal review, ADHS again worked with the STAB Work Group and STAB to finalize and obtain their approval of revised draft rules before proceeding to the formal rulemaking process.

As a result of this cooperative effort, ADHS has created rules for trauma center designation that represent the recommendations of STAB and the STAB Work Group; that meet the needs of the EMS, hospital, and urgent care communities; and that will protect and enhance public health and public health preparedness in Arizona.

The rules in the new 9 A.A.C. 25, Article 13 provide standards and establish the process for the designation of health care institutions as trauma centers at four different Levels. Designation represents a formal determination by ADHS that a health care institution has the resources and capabilities necessary to provide trauma services at a particular Level and is a trauma center. Designation as a Level I trauma center requires the most resources and capabilities, and the resources and capabilities required decrease as the designation Level increases.

Under the new rules, designation is voluntary. An owner is not required to obtain designation as a prerequisite to providing trauma services at the owner's health care institution and is not required to demonstrate the need for a trauma center in its health care institution's geographic area as part of the designation process. ADHS believes that this is consistent with ADHS's statutory authority because A.R.S. § 36-2225 does not indicate that designation is mandatory and does not prohibit a health care institution from providing trauma services if it is not a designated trauma center. Although the designation process is similar to a licensing process, the voluntary nature of designation results in its not being a "license" as defined in A.R.S. § 41-1001.

The rules allow for designation at a particular Level (Level I through Level IV) based on ACS verification at the same Level or based on a health care institution's meeting the state standards for the Level. The rules prescribe the state standards for Level I, II, and IV trauma centers in Exhibit I. The determination that a health care institution meets the state standards for designation as a Level I, II, or III trauma center is made through an ACS site visit. This means that an owner who desires to obtain designation as a Level I, II, or III trauma center for the owner's health care institution must arrange and pay for an ACS site visit. If ACS is requested to conduct a site visit as a "combined visit," ACS will make separate determinations of (1) eligibility for ACS verification and (2) whether a health care institution meets the state standards for designation. The determination that a health care institution meets the state standards for designation as a Level IV trauma center is made through an onsite survey of the health care institution conducted by ADHS.

The state standards for designation prescribed in Exhibit I are modeled after ACS's criteria for verification contained in the ACS publication *Resources for Optimal Care of the Injured Patient: 1999*, as subsequently amended by ACS, and are very similar to the standards adopted as guidelines in the Arizona EMS and Trauma System Plan for 2002-2005. Having ACS perform the site visits for designation as a Level I, II, or III trauma center, whether designation is based on ACS verification or on meeting the state standards, is consistent with the recommendations made by STAB and the STAB Work Group. STAB and the STAB Work Group also recommended that designation be available at all Levels based on ACS verification at the same Level.

In addition to establishing standards and a process for regular designation as a Level I, II, III, or IV trauma center, the rules establish a provisional designation to allow designation as a Level I, II, or III trauma center to be granted for a health care institution that has not compiled sufficient data related to the trauma services provided to be eligible to obtain an ACS site visit. This could be because the health care institution has not been providing organized trauma services or because it has only recently begun providing organized trauma services.

The rules also establish a grace period to allow each of the state's seven currently self-designated Level I trauma facilities to obtain initial designation as a Level I trauma center without first obtaining ACS verification as a Level I trauma facility or documentation from ACS establishing that the trauma facility meets the state standards for designation as a Level I trauma center.

In addition, the rules establish a process for modification of designation if a trauma center's owner desires to obtain a designation that requires fewer resources and capabilities than the trauma center's current designation.

ADHS intends to request that this rulemaking become effective immediately upon filing with the Office of the Secretary of State, as authorized under A.R.S. § 41-1032(A)(4), because the rules will provide a benefit to the public, and a penalty is not associated with a violation of the rules.

ADHS believes that the establishment of a formal state designation process is a cornerstone in the development of a more cohesive and effective state EMS and trauma system. Official determination of the resources and capabilities possessed by health care institutions providing trauma services will enable health care providers, including EMS providers, to ensure that each trauma patient is cared for at a health care institution with the resources and capabilities that match the patient's treatment needs, resulting in the best and most cost-effective care possible for the patient and in the best and most cost-effective use of the health care institution's resources. The following quoted material, from the US. Department of Health and Human Services Health Resources and Services Administration, the American

Trauma Society, and the American Association for the Surgery of Trauma publication *When it Matters Most: Trauma Centers, Part of Your Community, There to Save Lives*, explains the concept well:

Trauma centers must be part of a larger Trauma System to ensure the right patient is taken to the right hospital in the right amount of time to give them the greatest chance of survival. The Emergency Medical System (EMS)—911 dispatchers, emergency medical technicians on ambulances and helicopters—works to identify the severity of injury and takes those with less life-threatening injuries to emergency rooms and the most severely injured to a Trauma Center.

Trauma Systems are designed to take maximum advantage of the "golden hour"—the sixty critical minutes when a life hangs in the balance. Getting full-fledged trauma care within an hour after the injury occurred can mean the difference between life or death—or whether you fully recover.

. . .

Each year, nearly 150,000 Americans die from injuries. Injury is the leading cause of death and disability among children and adults in the country. Does having a well-organized, viable system of trauma care in your area make a difference? By any measure, the answer is yes.

Trauma Systems can reduce the preventable death rate by 20-30 percent; some say even up to 50 percent. For example, studies of Trauma Systems in the United States, where the most severely injured patients are directed to specialized Trauma Centers showed that the benefit of an organized system of trauma care can reduce the risk of death by greater than 50 percent among seriously injured trauma patients. As an added benefit, these survivors have shorter hospital stays, freeing up resources for other needs.

A state designation process will help to develop Arizona's EMS and trauma system so that trauma patients are treated in the most appropriate settings for their needs, and fewer trauma patients with severe trauma injuries will be unable to obtain the level of care needed in a timely manner because of a lack of resources. ADHS believes that developing and enhancing the Arizona EMS and trauma system through trauma center designation will result in many trauma patients' having better outcomes and even in the survival of some trauma patients who might not have survived in the absence of a developed EMS and trauma system.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

ADHS has read and is relying on information in American College of Surgeons Committee on Trauma, *Resources for Optimal Care of the Injured Patient: 1999* (1998). Although ADHS does not believe that this ACS publication is a study as that term is used in the Administrative Procedure Act, ADHS believes that a number of ACS's recommendations in the publication are based upon information derived from studies. The publication is available to purchase from ACS at 633 N. Saint Clair St., Chicago, IL 60611-3211 or http://www.facs.org/trauma/index.html.

ADHS has read and is relying on information in U.S. Department of Health and Human Services Health Resources and Services Administration, American Trauma Society, and American Association for the Surgery of Trauma, *When it Matters Most: Trauma Centers, Part of Your Community, There to Save Lives* (2004). Although ADHS does not believe that this publication is a study, the publication refers to studies. The publication is available, free of charge, from the American Trauma Society at 8903 Presidential Parkway, Suite 512, Upper Marlboro, MD 20772, or at http://www.amtrauma.org/uploads/1089662159249.pdf.

ADHS has read and, consistent with the recommendations of STAB and the STAB Work Group, is not relying on information in the following studies presented to ADHS as justification for allowing pediatric-only Level I trauma centers to have trauma surgeons on call and able to arrive at a trauma center within a 15-20 minute response time rather than requiring a trauma surgeon or senior surgical resident to be in-house at all times at a pediatric Level I trauma center:

Michael L. Nance, MD, et al., Blunt Renal Injuries in Children Can Be Managed Nonoperatively: Outcome in a Consecutive Series of Patients, 57 J. TRAUMA 474 (2004), available to purchase at http://www.jtrauma.com; and

Barbara A. Gaines, MD, & Henri R. Ford, MD, *Abdominal and Pelvic Trauma in Children*, 30 CRITICAL CARE MED. S416 (2002), available to purchase at http://www.ccmjournal.com.

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The rules will result in costs to ADHS, members of STAB, members of the STAB Work Group, and each owner who applies for trauma center designation for the owner's health care institution. The rules may also result in costs to the Arizona Health Care Cost Containment System (AHCCCS). ADHS does not believe that any other person will incur costs as a result of the new rules.

Notices of Proposed Rulemaking

The rules will benefit ADHS, members of STAB and the STAB Work Group, each owner who obtains trauma center designation for the owner's health care institution, EMS providers, trauma patients and their loved ones, and ACS. ADHS does not believe that any other persons will benefit from the new rules.

As used in this summary, "minimal" means less than \$1,000; "moderate" means \$1,000 to \$9,999; "substantial" means \$10,000 or more; and "significant" means meaningful or important, but not easily subject to quantification.

ADHS has incurred substantial costs from the rulemaking process, and each member of STAB and the STAB Work Group who actively participated in the rulemaking process has incurred moderate costs from the time spent. Each member of STAB and the STAB Work Group also received a significant benefit from the rulemaking process because ADHS was receptive to STAB and STAB Work Group suggestions throughout the rulemaking process and created rules consistent with the groups' recommendations.

ADHS believes that the existence of a trauma center designation process in Arizona will result in no burden to a very minimal burden to AHCCCS from adjusting its operations so that Trauma and Emergency Services Fund monies are distributed only to designated Level I trauma centers and from processing additional applications for and distributing monies to any Level I trauma centers beyond the seven currently self-designated Level I trauma facilities. Because the seven currently self-designated Level I trauma facilities are receiving Trauma and Emergency Services Fund monies for unrecovered trauma center readiness costs from AHCCCS, and AHCCCS will no longer distribute these monies to non-designated trauma facilities after ADHS begins designating trauma centers, the existence of a trauma center designation process in Arizona may result in a substantial impact to the owners of the seven currently self-designated Level I trauma facilities. If any of the seven owners does not obtain designation as a Level I trauma center, that owner will incur a substantial cost from the loss of eligibility for the Trauma and Emergency Services Fund monies. For FY2004, each of these owners received more than \$1 million from this Fund for unrecovered trauma center readiness costs

ADHS believes that the existence of a trauma center designation process in Arizona may result in a substantial cost to University Medical Center (UMC), if UMC does not obtain designation as a trauma center. UMC has been designated as a trauma center by the Pima County Board of Supervisors. In the absence of a state designation process, ADHS believes that UMC's designation by the Pima County Board of Supervisors made UMC eligible to bill for trauma team activations on the UB-92 form using revenue code 068X. A health care institution may only bill for trauma team activations using revenue code 068X if the health care institution has either ACS verification or designation from the state or local government authority authorized to designate. Because the Arizona Legislature has provided the statutory authority for trauma center designation to ADHS, not the counties, ADHS believes that having a state designation process in place will render UMC ineligible to bill for trauma team activations using revenue code 068X, unless UMC obtains designation from ADHS. A representative of the National Foundation for Trauma Care estimated that, depending on patient volume and the trauma center Level, billing for trauma team activations using revenue code 068X could result in an additional \$500,000 in annual reimbursement for a trauma facility.

Having a state trauma center designation process in Arizona will result in a significant benefit to ADHS, owners who obtain trauma center designation for their health care institutions, EMS providers, and trauma patients and their loved ones because establishing a formal trauma center designation process is a cornerstone in developing a cohesive and effective statewide EMS and trauma system.

An owner of a health care institution who applies for designation as a Level I, II, or III trauma center will incur a substantial cost from obtaining an ACS site visit to obtain either ACS verification or an ACS determination that the owner's health care institution meets the state standards for designation. The estimated cost of an ACS site visit, conducted by two surgeons, is approximately \$12,700 (including the ACS administrative verification fee, an honorarium for each surgeon, the travel expenses for each surgeon, and the cost of a dinner meeting). In addition to the actual costs associated with the site visit itself, an owner will also incur costs from the administrative process of applying and coordinating the site visit with ACS.

ADHS will receive a substantial benefit from having ACS conduct the site visits for designation as a Level I, II, or III trauma center. For ADHS to conduct these site visits, ADHS would need to obtain the services and pay for the travel expenses of at least one out-of-state trauma surgeon and would need to use staff time to coordinate the site visit with the surgeon and applicants. ADHS believes that trauma patients and their loved ones will also receive a significant benefit from having ACS conduct the site visits for designation as a Level I, II, or III trauma center because ACS is the leading national authority on the resources and capabilities necessary to operate an effective trauma facility. ACS's involvement in the designation process for Level I, II, and III trauma centers should enhance Arizona's trauma system.

ACS will receive a moderate benefit from each application for designation as a Level I, II, or III trauma center, from the \$2,800 ACS administrative verification fee received for a site visit.

An owner who chooses to obtain ACS verification as a Level IV trauma facility to obtain designation as a Level IV trauma center will incur a substantial cost from the ACS site visit, as described above. An owner who chooses to obtain designation as a Level IV trauma center based on meeting the state standards will incur only a minimal cost from the time spent preparing for, and with ADHS during, an ADHS onsite survey. Allowing for designation as a Level IV trauma center without ACS involvement represents a potentially substantial benefit to an owner who desires

to obtain designation as a Level IV trauma center. ADHS, however, will incur substantial costs as a result of this. To implement this, ADHS is establishing a position for and will employ one grade 21 FTE surveyor to conduct onsite surveys. ADHS estimates that the annual cost of employing one grade 21 FTE is \$36,547-61,895 in salary plus approximately another \$12,182-20,632 in employee-related expenses, for a total cost of approximately \$48,729-82,527. This employee will also conduct investigations, which may include announced or unannounced onsite surveys.

Allowing an owner of one of the seven currently self-designated Level I trauma facilities to obtain designation as a Level I trauma center without first obtaining either ACS verification as a Level I trauma facility or documentation issued by ACS stating that the owner's health care institution meets the state standards for a Level I trauma center, under the grace period Section, may result in a substantial benefit to each of the six currently self-designated Level I trauma facilities that do not already hold ACS verification, because each is eligible to obtain designation as a Level I trauma center without first paying for an ACS site visit. This will probably not result in a benefit to St. Joseph's Hospital and Medical Center (St. Joe's), because St. Joe's already holds ACS verification as a Level I trauma facility and thus is already eligible to obtain regular designation as a Level I trauma center based on its ACS verification.

The grace period Section also allows an owner of one of the seven currently self-designated Level I trauma facilities to choose to meet the state standards for a Level II trauma center, rather than those for a Level I trauma center, during the term of the initial Level I designation granted under the grace period Section. This may result in a substantial benefit to each of the six currently self-designated Level I trauma facilities that do not currently hold ACS verification because each will be able to obtain initial designation as a Level I trauma center without having the resources and capabilities required only for Level I trauma centers (most of which would result in a substantial cost individually). The grace period will allow these trauma centers time to come into compliance with those requirements for a Level I trauma center that are not currently met.

Allowing an owner whose health care institution has not produced at least 12 consecutive months of data related to trauma services provided at the health care institution, and who cannot yet comply with the eligibility requirements for regular designation as a Level I, II, or III trauma center, to obtain an 18-month provisional designation will result in a substantial benefit to each owner who wants to begin providing organized trauma services or whose health care institution has been providing organized trauma services for only a short period of time and who desires to obtain designation as a Level I, II, or III trauma center. ACS will not perform a site visit for verification or a combined visit unless a health care institution has been providing trauma services and can provide trauma-related data for at least the past 9-12 months. Also, at least in the central region of Arizona, regional protocols require EMS providers to take trauma patients only to specified trauma facilities. Once designation begins, these protocols will require EMS providers in the central region to take trauma patients only to designated trauma centers. This would make it impossible for a new trauma facility to establish the trauma-related data necessary to obtain an ACS site visit. Without an ACS site visit, it is not possible to obtain designation as a Level I, II, or III trauma center. The rules eliminate this dilemma by creating a shorter term provisional designation that allows a health care institution to be designated (and thus to receive trauma patients from EMS providers) so that it can establish the trauma-related data necessary to obtain the ACS site visit necessary to obtain regular designation. The rule's allowing for an extension of provisional designation will also result in a substantial benefit to each owner that holds a provisional designation that will expire on its face before an ACS site visit of the owner's trauma center has been completed.

The rules provide that regular designation issued based on ACS verification expires on the expiration date of the ACS verification and that regular designation issued based on meeting the state standards expires after three years. ACS verification is good for three years. For renewal of designation as a Level I, II, or III trauma center, an owner is again required to provide documentation of either ACS verification or ACS's determination that the owner's health care institution meets the state standards. This will result in a substantial cost to an owner who applies for renewal of designation as a Level I, II, or III trauma center, from obtaining an ACS site visit either for re-verification or an ACS determination that the owner's health care institution meets the state standards. The cost of an ACS site visit for reverification, conducted by two surgeons, is approximately \$12,100 (including the \$2,200 ACS administrative re-verification fee, an honorarium for each surgeon, the travel expenses for each surgeon, and the cost of a dinner meeting). In addition to the actual costs associated with the site visit itself, an owner will also incur costs from the administrative process of applying and coordinating the site visit with ACS. For the reasons stated previously, this will result in a substantial overall benefit to ADHS and a moderate benefit to ACS per renewal application.

Allowing an owner who desires to obtain a designation that requires fewer resources and capabilities than the current designation to obtain modified designation at a state Level consistent with the resources and capabilities that the owner intends to have at the trauma center will result in a substantial benefit to an owner who is unable to maintain the resources and capabilities necessary for the current designation, but who desires to have the owner's trauma center remain designated, because ADHS does not require an ACS site visit to issue modified designation. The owner is instead required to attest that the owner will ensure, and then to ensure, that the owner's trauma center meets the state standards for the Level of the modified designation.

The rules require the owner of a trauma center to ensure that the owner's trauma center meets the state standards or, if applicable, the ACS standards. This will result in a substantial cost to each owner who holds designation as a trauma center because the state standards and ACS standards require a number of resources and capabilities, at a substantial

cost. The extent of the cost depends upon which resources and capabilities already exist at an owner's health care institution. Because designation is voluntary, however, it is an owner's decision to obtain designation that will actually result in the costs to the owner, not the rule itself. This requirement will result in a significant benefit to ADHS and to trauma patients and their loved ones because it will help to ensure that only committed owners whose trauma centers meet the applicable standards for designation will be designated.

The rules require the owner of a trauma center to ensure that data related to the trauma services provided are submitted to ADHS's Trauma Registry as required by ADHS. This will result in no cost to a substantial cost to the owner of a trauma center. A.R.S. § 36-2221(A) already requires each acute care hospital that provides in-house 24-hour daily dedicated trauma surgical services to submit to ADHS a uniform data set for trauma patients as prescribed by ADHS. Thus, the seven currently self-designated Level I trauma facilities are already statutorily required to provide, and are providing, data to the Trauma Registry and should incur no additional costs as a result of this provision. In addition, A.R.S. § 36-2221 provides that advanced life support base hospitals that are not trauma centers may also submit this data to the Trauma Registry. Each owner of a trauma center whose health care institution is not already statutorily required to submit data to the Trauma Registry and whose health care institution is not currently submitting data to the Trauma Registry will incur a minimal-to-substantial cost from the staff time spent ensuring that data are submitted to the Trauma Registry as required by ADHS. The costs will depend on the database software used by the owner, the quality of the data entered into the trauma center's own database, and the staff time needed to ensure that the data to be submitted to ADHS comply with ADHS requirements. ADHS is currently in the process of standardizing the data set to be used and assisting currently submitting entities with a transition to a standardized data set, which should help to minimize the costs resulting from this provision.

The rules also require the owner of a trauma center to ensure that the owner and the trauma center staff comply with the applicable provisions of A.R.S. Title 36, Chapter 21.1 and the new rules and with all applicable federal and state laws relating to confidentiality of information. This should result in no cost to an owner because the owner and the trauma center staff should already be complying with all applicable laws. This may result in a substantial cost, however, if an owner fails to ensure compliance.

The rules also require ADHS to comply with all applicable federal and state laws relating to confidentiality of information, which should result in no impact to ADHS because ADHS is already obligated to comply with these laws.

Finally, the rules prescribe the state standards (the resources and capabilities required) for designation as a Level I, II, III, or IV trauma center. Meeting the state standards for designation may result in a substantial cost to the owner of a health care institution, depending on which resources and capabilities already exist at the owner's health care institution. Because designation is voluntary, however, the cost of meeting the prescribed state standards is the direct result of an owner's choice to pursue designation for the owner's health care institution, not the direct result of the rules themselves. The state standards for designation will result in a significant benefit to ADHS and to trauma patients and their loved ones because the state standards will help to ensure that trauma patients are being taken to appropriate health care institutions that have the resources and capabilities necessary to provide quality trauma services.

ADHS does not believe that any small businesses will be subject to the rules or that there is a less intrusive or less costly alternative method of achieving the purpose of the rulemaking.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Vicki Conditt, Trauma and EMS System Development Section Chief

Address: Arizona Department of Health Services

Bureau of Emergency Medical Services

150 N. 18th Ave., Suite 540

Phoenix, AZ 85007

Telephone: (602) 364-3155

Fax: (602) 364-3568

E-mail: conditio@ardha.go

E-mail: conditv@azdhs.gov

or

Name: Kathleen Phillips, Rules Administrator

Address: Arizona Department of Health Services

Office of Administrative Rules 1740 W. Adams St., Suite 202

Phoenix, AZ 85007

Telephone: (602) 542-1264 Fax: (602) 364-1150

E-mail: phillik@azdhs.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

ADHS has scheduled the following oral proceeding:

Date: July 25, 2005 Time: 10:00 a.m.

Location: Arizona Department of Health Services

150 N. 18th Ave., Room 540A

Phoenix, AZ 85007

Nature: Oral proceeding

Individuals with a disability may request a reasonable accommodation by contacting Joy Lehman at (602) 364-0781 or lehmanj@azdhs.gov. A request should be made as early as possible to allow sufficient time to arrange for the accommodation.

Written comments on the proposed rulemaking or the preliminary economic, small business, and consumer impact summary may be submitted to either individual listed in items #4 and #9 until the close of record at 5:00 p.m. on July 29, 2005.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

ARTICLE 13. TRAUMA CENTER DESIGNATION

Section	
R9-25-1301.	Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1302.	Eligibility for Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1303.	Grace Period for Self-Designated Level I Trauma Facilities (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-
	2225(A)(4))
R9-25-1304.	Initial Application and Designation Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1305.	Eligibility for Provisional Designation; Provisional Designation Process (A.R.S. §§ 36-2202(A)(4), 36-
	2209(A)(2), and 36-2225(A)(4))
R9-25-1306.	Designation Renewal Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1307.	Term of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1308.	Changes Affecting Designation Status (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1309.	Modification of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1310.	Onsite Survey for Designation as a Level IV Trauma Center Based on Meeting the State Standards (A.R.S. §§
	36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1311.	Investigations (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4) and (5))
R9-25-1312.	Denial or Revocation of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
R9-25-1313.	Trauma Center Responsibilities (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4), (5), and (6))
R9-25-1314.	Confidentiality of Information (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4) and (6))
R9-25-1315.	Application Processing Time Periods (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
Table 1.	Application Processing Time Periods (in days) (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))
Exhibit I.	Arizona Trauma Center Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

ARTICLE 13. TRAUMA CENTER DESIGNATION

R9-25-1301. Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

The following definitions apply in this Article, unless otherwise specified:

- "ACS" means the American College of Surgeons Committee on Trauma.
- "ACS site visit" means an onsite inspection of a trauma facility conducted by ACS for purposes of determining compliance with ACS trauma facilities criteria, or ACS trauma facilities criteria and state standards, at the Level of desig-
- "Administrative completeness time period" means the number of days from the Department's receipt of an application until the Department determines that the application contains all of the items of information required by rule to be submitted with an application.
- 'ATLS" means the ACS Advanced Trauma Life Support Course.
- "Available" means accessible for use.

 "Chief administrative officer" means an individual assigned to control and manage the day-to-day operations of a health care institution on behalf of the owner or the body designated by the owner to govern and manage the health care institution.
- "CME" means continuing medical education courses for physicians.
- "Comply with" means to satisfy the requirements of a stated provision.
- "CT" means computed tomography.
- 10. "Current" means up-to-date and extending to the present time.
- 11. "CVP" means central venous pressure.
- 12. "Department" means the Arizona Department of Health Services.
- 13. "Designation" means a formal determination by the Department that a health care institution has the resources and capabilities necessary to provide trauma services at a particular Level and is a trauma center.
- 14. "EMS" means emergency medical services.

 15. "Health care institution" has the same meaning as in A.R.S. § 36-401.
- 16. "Hospital" has the same meaning as in A.A.C. R9-10-201.
- 17. "ICU" means intensive care unit.
- 18. "In compliance with" means satisfying the requirements of a stated provision.
- 19. "In-house" means on the premises at the health care institution.
- 20. "ISS" means injury severity score, the sum of the squares of the abbreviated injury scale scores of the three most severely injured body regions.
- 21. "Major resuscitation" means a patient:
 - a. If an adult, with a confirmed blood pressure <90 at any time or, if a child, with confirmed age-specific hypotension;
 - With respiratory compromise, respiratory obstruction, or intubation, if the patient is not transferred from another health care institution;
 - Who is transferred from another hospital and is receiving blood to maintain vital signs;
 - Who has a gunshot wound to the abdomen, neck, or chest;
 - Who has a Glasgow Coma Scale score <8 with a mechanism attributed to trauma; or
 - Who is determined by an emergency physician to be a major resuscitation.
- 22. "Meet the ACS standards," "meeting the ACS standards," or "meets the ACS standards" means be operated, being operated, or is operated in compliance with each applicable criterion for verification as required by ACS for verifica-
- 23. "Meet the state standards," "meeting the state standards," or "meets the state standards" means be operated, being operated, or is operated in compliance with each applicable criterion listed in Exhibit I at least as frequently or consistently as required by the minimum threshold stated for the criterion in Exhibit I or at least 95% of the time, whichever
- 24. "On-call" means assigned to respond and, if necessary, come to a health care institution when called by health care institution personnel.
- 25. "Owner" means one of the following:
 - a. For a health care institution licensed under 9 A.A.C. 10, the licensee;
 - b. For a health care institution operated under federal or tribal laws, the administrative unit of the U.S. government or sovereign tribal nation operating the health care institution.
- 26. "Person" means:
 - a. An individual:
 - b. A business organization such as an association, cooperative, corporation, limited liability company, or partner-
 - c. An administrative unit of the U.S. government, state government, or a political subdivision of the state.

- 27. "Personnel" means an individual providing medical services, nursing services, or health-related services to a patient.
- 28. "PGY" means postgraduate year, a classification for residents in postgraduate training indicating the year that they are in during their post-medical-school residency program.
- 29. "Self-designated Level I trauma facility" means a health care institution that as of July 1, 2004, met the definition of a Level I trauma center under A.A.C. R9-22-2101(F)(1).
- 30. "SICU" means surgical intensive care unit.
- 31. "Signature" means:
 - a. A handwritten or stamped representation of an individual's name or a symbol intended to represent an individual's name, or
 - b. An "electronic signature" as defined in A.R.S. § 44-7002.
- 32. "Substantive review time period" means the number of days after completion of the administrative completeness time period during which the Department determines whether an application and owner comply with all substantive criteria required by rule for issuance of an approval.
- 33. "Transfer agreement" means a written contract between the owners of two health care institutions in which one owner agrees to have its health care institution receive a patient from the other owner's health care institution if the patient falls within specified criteria related to diagnosis, acuity, or treatment needs.
- 34. "Trauma center" has the same meaning as in A.R.S. § 36-2225.
- 35. "Valid" means that a license, certification, or other form of authorization is in full force and effect and not suspended or otherwise restricted.
- 36. "Verification" means formal confirmation by ACS that a health care institution has the resources and capabilities necessary to provide trauma services as a Level I, Level II, Level III, or Level IV trauma facility.
- 37. "Working day" means the period between 8:00 a.m. and 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.

R9-25-1302. Eligibility for Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. To be eligible to obtain designation for a health care institution, an owner shall:
 - 1. If applying for designation as a Level I trauma center:
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level I trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level I trauma center;
 - 2. <u>If applying for designation as a Level II trauma center:</u>
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level II trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level II trauma center;
 - 3. <u>If applying for designation as a Level III trauma center:</u>
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level III trauma facility; or
 - ii. Have current documentation issued by ACS stating that the health care institution meets the state standards for a Level III trauma center; and
 - 4. <u>If applying for designation as a Level IV trauma center:</u>
 - a. Comply with one of the following:
 - i. Hold a current and valid regular license for the health care institution to operate, issued by the Department

Notices of Proposed Rulemaking

- under 9 A.A.C. 10; or
- ii. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution under federal or tribal law; and
- b. Comply with one of the following:
 - i. Hold current verification for the health care institution as a Level IV trauma facility; or
 - ii. Demonstrate, during an onsite survey of the health care institution conducted by the Department as described in R9-25-1310, that the health care institution meets the state standards for a Level IV trauma center.
- **B.** To be eligible to retain designation for a health care institution, an owner shall:
 - 1. Maintain a current and valid regular license for the health care institution to operate, if applicable; and
 - 2. Comply with the trauma center responsibilities in R9-25-1313.

<u>R9-25-1303.</u> <u>Grace Period for Self-Designated Level I Trauma Facilities (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))</u></u>

- A. Within 90 days after the effective date of this Article, the owner of a self-designated Level I trauma facility who desires to obtain designation for the self-designated Level I trauma facility as a Level I trauma center under this Article shall apply for initial designation as a Level I trauma center under R9-25-1304.
- **B.** An owner who applies for designation based on eligibility under this Section shall attest to one of the following in the application for initial designation:
 - 1. That the owner's health care institution will meet the state standards for a Level I trauma center during the initial designation period, or
 - 2. That the owner's health care institution will meet the state standards for a Level II trauma center during the initial designation period.
- C. For an application submitted by an owner described under subsection (A), the Department shall waive the eligibility requirement of R9-25-1302(A)(1)(b) and grant designation as a Level I trauma center if the other requirements for designation are met.
- D. An owner who obtains designation based on eligibility under this Section shall, during the term of the designation, ensure that the owner's trauma center meets the state standards that were the subject of the owner's attestation described in subsection (B).
- E. An owner described under subsection (A) who obtains initial designation as a Level I trauma center and who desires to retain designation shall apply for renewal of designation under R9-25-1306.
- F. To obtain renewal of designation under R9-25-1306, an owner described under subsection (A) shall comply with R9-25-1302(A)(1)(b)(i) or (ii) and R9-25-1306.
- G. During the term of an initial designation granted to an owner based on eligibility under this Section, the Department may:

 1. Investigate the owner's trauma center, as provided under R9-25-1311; and
 - 2. Revoke the owner's designation, as provided under R9-25-1312.
- H. This Section expires on January 1, 2009.

R9-25-1304. Initial Application and Designation Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. An owner applying for initial designation shall submit to the Department an application including:
 - 1. An application form provided by the Department containing:
 - <u>a.</u> The name, address, and main telephone number of the health care institution for which the owner seeks designation;
 - b. The owner's name, address, and telephone number and, if available, fax number and e-mail address;
 - c. The name and telephone number and, if available, fax number and e-mail address of the chief administrative officer for the health care institution for which the owner seeks designation;
 - d. The designation Level for which the owner is applying:
 - e. If the owner holds verification for the health care institution for which designation is sought, the Level of verification held and the effective and expiration dates of the verification;
 - <u>f.</u> The asserted basis for designation:
 - i. The owner holds verification for the health care institution,
 - ii. The owner's health care institution meets the state standards, or
 - iii. The owner is eligible for the grace period under R9-25-1303;
 - g. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, the hospital or health care institution license number for the health care institution for which designation is sought;
 - h. If applying for designation as a Level I, Level II, or Level III trauma center, the name and telephone number and, if available, fax number and e-mail address of the health care institution's trauma medical director;
 - i. The name, title, address, and telephone number of the owner's statutory agent or the individual designated by the owner to accept service of process and subpoenas;

- j. Attestation that the owner knows all applicable requirements in A.R.S. Title 36, Chapter 21.1, and this Article;
- k. Attestation that the information provided in the application, including the information in the documents attached to the application form, is accurate and complete; and
- 1. The dated signature of:
 - i. If the owner is an individual, the individual;
 - ii. If the owner is a corporation, an officer of the corporation;
 - iii. If the owner is a partnership, one of the partners;
 - iv. If the owner is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
 - v. If the owner is an association or cooperative, a member of the governing board of the association or cooperative;
 - vi. If the owner is a joint venture, one of the individuals signing the joint venture agreement;
 - vii. If the owner is a governmental agency, the individual in the senior leadership position with the agency or an individual designated in writing by that individual; and
 - viii. If the owner is a business organization type other than those described in subsections (A)(1)(l)(ii) through (vi), an individual who is a member of the business organization;
- 2. Unless the owner is an administrative unit of the U.S. government or a sovereign tribal nation, a copy of the current regular hospital or health care institution license issued by the Department for the health care institution for which designation is sought;
- 3. If applying for designation based on verification, documentation issued by ACS establishing that the owner holds current verification for the health care institution at the Level of designation sought and showing the effective and expiration dates of the verification; and
- 4. If applying for designation as a Level I, Level II, or Level III trauma center based on meeting the state standards, current documentation issued by ACS establishing that the owner's health care institution meets the state standards listed in Exhibit I for the Level of designation sought.
- **B.** The Department shall process an application as provided in R9-25-1315.
- C. The Department shall approve designation if the Department determines that an owner is eligible for designation as described in R9-25-1302.

R9-25-1305. Eligibility for Provisional Designation; Provisional Designation Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. The owner of a health care institution may apply for one 18-month provisional designation as a Level I, Level II, or Level III trauma center if:
 - 1. When the owner applies for provisional designation, the owner's health care institution has not produced at least 12 consecutive months of data related to trauma services provided at the health care institution; and
 - 2. The owner cannot comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b).
- B. To be eligible to obtain provisional designation for a health care institution, an owner shall:
 - 1. Comply with one of the following:
 - a. Hold a current and valid regular license for the health care institution to operate as a hospital, issued by the Department under 9 A.A.C. 10, Article 2; or
 - b. Be an administrative unit of the U.S. government or a sovereign tribal nation operating the health care institution as a hospital under federal or tribal law; and
 - 2. Make the attestations described in subsection (C)(2).
- C. An owner applying for provisional designation shall submit to the Department an application including:
 - 1. An application form that contains the information and items listed in R9-25-1304(A)(1)(a) through (A)(1)(d), (A)(1)(g) through (A)(1)(l), and (A)(2); and
 - 2. Attestation that:
 - a. The owner's health care institution has the resources and capabilities necessary to meet the state standards for the Level of designation sought and will meet the state standards for the Level of designation sought during the term of the provisional designation; and
 - b. During the term of the provisional designation, the owner will:
 - i. Ensure that the trauma center meets the state standards;
 - ii. Apply for verification for the trauma center; and
 - iii. Provide to the Department, within 30 days after applying for verification, documentation issued by ACS establishing that the owner has applied for verification.
- **D.** The Department shall process an application submitted under this Section as provided in R9-25-1315.
- E. The Department shall approve provisional designation if the Department determines that an owner is eligible for provisional designation as described in subsection (B).

Notices of Proposed Rulemaking

- F. To be eligible to retain provisional designation for a health care institution, an owner shall:
 - 1. Comply with subsection (B)(1)(a) or (b);
 - 2. Comply with the trauma center responsibilities in R9-25-1313;
 - 3. Apply for verification for the trauma center; and
 - 4. Provide to the Department, within 30 days after applying for verification, documentation issued by ACS establishing that the owner has applied for verification.
- **G.** An owner who holds provisional designation and who desires to retain designation shall, before the expiration date of the provisional designation:
 - 1. If the owner can comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for initial designation under R9-25-1304; or
 - 2. If the owner cannot comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b), apply for an extension of the provisional designation under subsection (H).
- H. An owner who holds provisional designation and who will not be able to comply with R9-25-1302(A)(1)(b), (A)(2)(b), or (A)(3)(b) on the expiration date of the provisional designation may apply to the Department, on a form provided by the Department, for one 180-day extension of the provisional designation and shall include with the application documentation issued by ACS showing the owner's progress in obtaining an ACS site visit.
- I. The Department shall grant an extension if an owner has provided documentation issued by ACS:
 - 1. Establishing that the owner has applied for verification; and
 - 2. Showing the owner's progress in obtaining an ACS site visit.
- J. The Department may:
 - 1. Investigate, as provided under R9-25-1311, a trauma center that is the subject of a provisional designation; and
 - 2. Revoke, as provided under R9-25-1312, a provisional designation.

R9-25-1306. Designation Renewal Process (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. At least 60 days before the expiration date of a current designation, an owner who desires to obtain renewal of designation shall submit to the Department an application including:
 - 1. An application form that contains the information listed in R9-25-1304(A)(1);
 - 2. If applying for renewal of designation as a Level I, Level II, or Level III trauma center based on meeting the state standards, one of the following:
 - <u>a.</u> Documentation issued by ACS no more than 60 days before the date of application establishing that the owner's trauma center meets the state standards listed in Exhibit I for the Level of designation sought; or
 - b. Documentation issued by ACS establishing that the owner has applied for verification for the trauma center, at the Level corresponding to the Level of designation sought, for the three-year period directly following the expiration of the owner's current designation; and
 - 3. If applying for renewal of designation based on verification, documentation issued by ACS establishing that the owner:
 - a. Holds verification for the trauma center, at the Level corresponding to the Level of designation sought, for the three-year period directly following the expiration of the owner's current verification and designation; or
 - b. Has applied for verification for the trauma center, at the Level corresponding to the Level of designation sought, for the three-year period directly following the expiration of the owner's current verification and designation.
- **B.** The Department shall process an application as provided in R9-25-1315.
- C. The Department shall renew designation if the Department determines that the owner is eligible to retain designation as described in R9-25-1302(B).
- **D.** The Department shall not renew designation based on verification or ACS's determination that a trauma center meets the state standards until the Department receives documentation that complies with subsection (A)(2)(a) or (A)(3)(a).

R9-25-1307. Term of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- **A.** The Department shall issue initial designation or renewal of designation:
 - 1. When based on verification, with a term beginning on the date of issuance and ending on the expiration date of the verification upon which designation is based; and
 - 2. When based on meeting the state standards or eligibility under R9-25-1303, with a term beginning on the date of issuance and ending three years later.
- **B.** The Department shall issue a provisional designation with a term beginning on the date of issuance and ending 18 months later and an extension of provisional designation with a term beginning on the expiration date of the provisional designation and ending 180 days later.
- C. The Department shall issue a modified designation with a term beginning on the date of issuance and ending on the expiration date of the designation issued before the application for modification of designation under R9-25-1309.
- **D.** If an owner submits an application for renewal of designation as described in R9-25-1306 before the expiration date of the current designation, or submits an application for extension of provisional designation as described in R9-25-1305 before

Notices of Proposed Rulemaking

the expiration date of the provisional designation, the current designation does not expire until the Department has made a final determination on the application for renewal of designation or extension of provisional designation.

R9-25-1308. Changes Affecting Designation Status (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. At least 30 days before the date of a change in a trauma center's name, the owner of the trauma center shall send the Department written notice of the name change.
- **B.** At least 90 days before a trauma center ceases to offer trauma services, the owner of the trauma center shall send the Department written notice of the intention to cease offering trauma services and the desire to relinquish designation.
- C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
 - 1. For a notice described in subsection (A), issue an amended designation that incorporates the name change but retains the expiration date of the current designation; or
 - 2. For a notice described in subsection (B), send the owner written confirmation of the voluntary relinquishment of designation, with an effective date consistent with the written notice.
- D. An owner of a trauma center shall notify the Department in writing within three working days after:
 - 1. The trauma center's hospital or health care institution license expires or is suspended, revoked, or changed to a provisional license;
 - 2. A change in the trauma center's verification status; or
 - 3. A change in the trauma center's ability to meet the state standards or, if designation is based on verification, to meet the ACS standards, that is expected to last for more than one week.
- E. An owner of a trauma center who obtains verification for the trauma center during a term of designation based on meeting the state standards may obtain a new initial designation based on verification, with a designation term based on the dates of the verification, by submitting an initial application as provided in R9-25-1304.

R9-25-1309. Modification of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. An owner of a trauma center who desires to obtain a designation that requires fewer resources and capabilities than the trauma center's current designation shall, at least 30 days before ceasing to provide trauma services consistent with the current designation, send the Department an application for modification of the trauma center's designation, including:
 - 1. The name, address, and main telephone number of the trauma center for which the owner seeks modification of designation;
 - 2. The owner's name, address, and telephone number and, if available, fax number and e-mail address;
 - 3. A list of the applicable ACS or state criteria for the current designation with which the owner no longer intends to comply;
 - 4. An explanation of the changes being made in the trauma center's resources or operations related to each criterion listed under subsection (A)(3):
 - 5. The state Level of designation requested;
 - 6. Attestation that the owner knows the state standards for the Level of designation requested and will ensure that the trauma center meets the state standards if modified designation is issued;
 - 7. Attestation that the information provided in the application is accurate and complete; and
 - 8. The dated signature of the owner, as prescribed in R9-25-1304(A)(1)(1).
- **B.** The Department shall process an application as provided in R9-25-1315.
- C. The Department shall issue a modified designation if the Department determines that, with the changes being made in the trauma center's resources and operations, the trauma center will meet the state standards for the Level of designation requested.
- **D.** An owner who obtains modified designation shall, during the term of the modified designation, ensure that the owner's trauma center meets the state standards that were the subject of the owner's attestation described in subsection (A)(6).
- **E.** The Department may:
 - 1. Investigate, as provided under R9-25-1311, a trauma center that is the subject of a modified designation; and
 - 2. Revoke, as provided under R9-25-1312, a modified designation.
- F. An owner who holds modified designation shall, before the expiration date of the modified designation:
 - 1. If the owner desires to retain designation based on the trauma center's meeting the state standards at the Level of the modified designation, apply for renewal of designation under R9-25-1306; or
 - 2. If the owner desires to obtain designation based on verification or based on the trauma center's meeting the state standards at a Level other than the Level of the modified designation, apply for initial designation under R9-25-1304.

R9-25-1310. Onsite Survey for Designation as a Level IV Trauma Center Based on Meeting the State Standards (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. Before issuing initial or renewal designation to an owner applying for designation as a Level IV trauma center based on meeting the state standards, the Department shall complete an announced onsite survey of the owner's health care institution that includes:
 - 1. Reviewing equipment and the physical plant;

Notices of Proposed Rulemaking

- 2. Interviewing personnel; and
- 3. Reviewing:
 - a. Medical records;
 - b. Patient discharge summaries;
 - c. Patient care logs;
 - d. Personnel rosters and schedules;
 - e. Performance-improvement-related documents other than peer review documents privileged under A.R.S. §§ 36-445.01 and 36-2403, including reports prepared as required under R9-10-204(B)(2) and the supporting documentation for the reports; and
 - f. Other documents relevant to the provision of trauma services as a Level IV trauma center and that are not privileged under federal or state law.
- B. A Department surveyor shall make a verbal report of findings to an owner upon completion of an onsite survey.
- C. Within 30 days after completing an onsite survey, the Department shall send to an owner a written report of the Department's findings, including a list of any deficiencies identified during the onsite survey and, unless subsection (F) applies, a request for a written corrective action plan.
- **D.** Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:
 - 1. A description of how the deficiency will be corrected, and
 - 2. A date of correction for the deficiency.
- E. The Department shall accept a written corrective action plan if it:
 - 1. Describes how each identified deficiency will be corrected, and
 - 2. <u>Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.</u>
- F. The Department shall provide an owner an opportunity to correct the deficiencies identified during an onsite survey unless the Department determines that the deficiencies are a direct risk to any person; the public health, safety, or welfare; or the environment.

R9-25-1311. Investigations (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4) and (5))

- A. If the Department determines based upon Trauma Registry data collected by the Department or receives a complaint alleging that a trauma center is not meeting the state standards or, if designation is based on verification, is not meeting the ACS standards, the Department shall conduct an investigation of the trauma center.
 - 1. The Department may conduct an announced or unannounced onsite survey as part of an investigation.
 - 2. Within 30 days after completing an investigation, the Department shall send to the owner of the trauma center investigated a written report of the Department's findings, including a list of any deficiencies identified during the investigation and, unless subsection (D) applies, a request for a written corrective action plan.
- **B.** Within 10 days after receiving a request for a written corrective action plan, an owner shall submit to the Department a written corrective action plan that includes for each identified deficiency:
 - 1. A description of how the deficiency will be corrected, and
 - 2. A date of correction for the deficiency.
- C. The Department shall accept a written corrective action plan if it:
 - 1. Describes how each identified deficiency will be corrected, and
 - 2. <u>Includes a date for correcting each deficiency as soon as practicable based upon the actions necessary to correct the deficiency.</u>
- **D.** The Department shall provide the owner of a trauma center an opportunity to correct the deficiencies identified during an investigation unless the Department determines that the deficiencies are a direct risk to any person; the public health, safety, or welfare; or the environment.

R9-25-1312. Denial or Revocation of Designation (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. The Department may deny or revoke designation if an owner:
 - 1. Has provided false or misleading information to the Department;
 - 2. Is not eligible for designation under R9-25-1302(A) or (B) or, if applicable, R9-25-1305(B) or (F);
 - 3. Fails to submit to the Department all of the information requested in a written request for additional information within the time prescribed in R9-25-1315 and Table 1;
 - 4. Fails to submit a written corrective action plan as requested and required under R9-25-1310 or R9-25-1311;
 - 5. Fails to comply with a written corrective action plan accepted by the Department under R9-25-1310 or R9-25-1311;
 - 6. Fails to allow the Department to enter the premises of the owner's health care institution, to interview personnel, or to review documents that are not documents privileged under federal or state law; or
 - 7. Fails to comply with any applicable provision in A.R.S. Title 36, Chapter 21.1, or this Article.

Notices of Proposed Rulemaking

- **B.** In determining whether to deny or revoke designation, the Department shall consider:
 - 1. The severity of each violation relative to public health and safety;
 - 2. The number of violations;
 - 3. The nature and circumstances of each violation;
 - 4. Whether each violation was corrected, the manner of correction, and the duration of the violation; and
 - 5. Whether the violations indicate a lack of commitment to having the trauma center meet the state standards or, if applicable, the ACS standards.
- C. If the Department denies or revokes designation, the Department shall send to the owner a written notice setting forth the information required under A.R.S. § 41-1092.03.
 - 1. An owner may file a written notice of appeal with the Department within 30 days after receiving a notice of denial or revocation, as provided in A.R.S. § 41-1092.03.
 - 2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

R9-25-1313. Trauma Center Responsibilities (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4), (5), and (6))

The owner of a trauma center shall ensure that:

- 1. The trauma center meets the state standards or, if designation is based on verification, meets the ACS standards;
- 2. Data related to the trauma services provided at the trauma center are submitted to the Department's Trauma Registry as required by the Department;
- 3. The owner and the trauma center staff comply with the applicable provisions of A.R.S. Title 36, Chapter 21.1, and this Article; and
- 4. The owner and the trauma center staff comply with all applicable federal and state laws relating to confidentiality of information.

R9-25-1314. Confidentiality of Information (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4) and (6)) The Department shall comply with all applicable federal and state laws relating to confidentiality of information.

R9-25-1315. Application Processing Time Periods (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

- A. The application processing time periods for each type of approval granted by the Department under this Article are listed in Table 1 and may be extended through a written agreement between an owner and the Department.
- **B.** The Department shall, within the administrative completeness time period specified in Table 1, review each application submitted for administrative completeness.
 - 1. If an application is incomplete, the Department shall send to the owner a written notice listing each deficiency and the information or items needed to complete the application.
 - 2. If an owner fails to submit to the Department all of the information or items listed in a notice of deficiencies within the time period specified in Table 1, the Department shall consider the application withdrawn.
- C. After determining that an application is administratively complete, the Department shall review the application for substantive compliance with the requirements for approval.
 - 1. The Department shall complete its substantive review of each application, and send an owner written notice of approval or denial, within the substantive review time period specified in Table 1.
 - 2. As part of the substantive review for an application for initial designation or renewal of designation as a Level IV trauma center based on meeting the state standards, the Department shall conduct an announced onsite survey of the health care institution or trauma center as described in R9-25-1310.
 - 3. An owner applying for renewal of designation who submits documentation of the owner's having applied for verification as permitted under R9-25-1306(A)(2)(b) or (A)(3)(b) shall submit to the Department during the substantive review time period documentation that complies with R9-25-1306(A)(2)(a) or (A)(3)(a).
 - 4. During the substantive review time period, the Department may make one written request for additional information, listing the information or items needed to determine whether to approve the application, including, for an owner applying for renewal described in subsection (C)(3), a request for documentation that complies with R9-25-1306(A)(2)(a) or (A)(3)(a).
 - 5. For an application for initial designation or renewal of designation as a Level IV trauma center based on meeting the state standards, a written request for additional information may include a request for a corrective action plan to correct any deficiencies identified during an onsite survey of the health care institution or trauma center.
 - 6. If an owner fails to submit to the Department all of the information or items listed in a written request for additional information, including, if applicable, a corrective action plan, within the time period specified in Table 1, the Department shall deny the application.
- **D.** In applying this Section, the Department shall:
 - 1. In calculating an owner's time to respond, begin on the postmark date of a notice of deficiencies or written request for additional information and end on the date that the Department receives all of the information or documents requested in the notice of deficiencies or written request for additional information; and

Notices of Proposed Rulemaking

- 2. In calculating the Department's time periods, not include any time during which the Department is waiting for an owner to submit information or documents to the Department as requested by the Department in a notice of deficiencies or written request for additional information.
- **E.** If the Department denies an application, the Department shall send to the owner a written notice of denial setting forth the information required under A.R.S. § 41-1092.03.
 - 1. An owner may file a written notice of appeal with the Department within 30 days after receiving the notice of denial, as provided in A.R.S. § 41-1092.03.
 - 2. An appeal shall be conducted according to A.R.S. Title 41, Chapter 6, Article 10.

<u>Table 1.</u> <u>Application Processing Time Periods (in days) (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))</u>

Type of Approval	Department's Administrative Completeness Time Period	Owner's Time to Respond to Notice of Deficiencies	Department's Substantive Review Time Period	Owner's Time to Respond to Written Request for Additional Information
Initial Designation (R9-25-1304)	<u>30</u>	<u>30</u>	90	<u>60</u>
Provisional Designation (R9-25-1305)	30	30	90	60
Extension of Provisional Designation (R9-25-1305)	15	30	15	30
Renewal of Designation (R9-25-1306)	30	30	90	120
Modification of Designation (R9-25-1309)	30	30	90	60

EXHIBIT I. ARIZONA TRAUMA CENTER STANDARDS (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2225(A)(4))

E = Essential and required

		Trauma Facilities Criteria	Levels	<u>S</u>		
			I	<u>II</u>	<u>III</u>	<u>IV</u>
<u>A.</u>	Ins	titutional Organization				
	<u>1.</u>	<u>Trauma program</u>	<u>E</u>	<u>E</u>	<u>E</u>	"
	<u>2.</u>	<u>Trauma service</u>	<u>E</u>	<u>E</u>	<u>E</u>	-1
	<u>3.</u>	<u>Trauma team</u>	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	<u>4.</u>	<u>Trauma program medical director</u> ¹	<u>E</u>	<u>E</u>	<u>E</u>	П
	<u>5.</u>	Trauma multidisciplinary committee	<u>E</u>	<u>E</u>	<u>E</u>	-
	<u>6.</u>	<u>Trauma coordinator/trauma program manager</u> ²	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
<u>B.</u>	Ho	spital Departments/Divisions/Sections				
	1.	Surgery	<u>E</u>	<u>E</u>	<u>E</u>	=
	<u>2.</u>	Neurological surgery	<u>E</u>	<u>E</u>	=	_
		a. Neurosurgical trauma liaison	<u>E</u>	<u>E</u>	=	-

				1	1	1
	<u>3.</u>	Orthopaedic surgery	<u>E</u>	<u>E</u>	<u>E</u>	Ξ
		a. Orthopaedic trauma liaison	<u>E</u>	<u>E</u>	<u>E</u>	=
	<u>4.</u>	Emergency medicine	<u>E</u>	<u>E</u>	<u>E</u>	Ξ
		<u>a.</u> Emergency medicine liaison ³	<u>E</u>	<u>E</u>	<u>E</u>	=
	<u>5.</u>	<u>Anesthesia</u>	<u>E</u>	<u>E</u>	<u>E</u>	_
<u>C.</u>	Cli	iical Capabilities				
	1.	Published on-call schedule for each listed specialty required in (C)(2) and (3)	<u>E</u>	<u>E</u>	<u>E</u>	-
	<u>2.</u>	Specialty immediately available 24 hours/day				
		a. General surgery ⁴	<u>E</u>	<u>E</u>	<u>E</u>	_
		i. Published back-up schedule	E	<u>E</u>	=	_
		ii. Dedicated to single hospital when on-call	<u>E</u>	<u>E</u>	=	-
		b. Anesthesia ⁵	<u> </u>	<u>E</u>	<u>E</u>	
		c. Emergency medicine ⁶	<u>–</u> <u>Е</u>	<u>E</u>	<u>E</u>	
	3.	On-call and promptly available 24 hours/day ⁷				=
	<u> </u>	a. Cardiac surgery ⁸	<u>E</u>	_	_	
		b. Hand surgery	<u>E</u>	<u>=</u>	=	=
		c. Microvascular/replant surgery	<u>E</u>		=	=
		d. Neurologic surgery	<u>E</u> E	<u>=</u>	=	=
		i. Dedicated to one hospital or back-up call	<u>E</u>	<u>E</u>	=	=
		e. Obstetrics/gynecologic surgery	<u>E</u>		=	=
		f. Ophthalmic surgery	<u>E</u>	<u> </u>	=	=
		0	<u>Е</u> <u>Е</u>	<u>E</u>	=	=
						=
		h. Orthopaedic surgery i. Dedicated to one hospital or back-up call	<u>E</u>	<u>E</u>	<u>E</u>	=
			<u>E</u>	<u>E</u>	=	=
		i. Plastic surgery	<u>E</u>	<u>E</u>	=	=
		j. Critical care medicine	<u>E</u>	<u>E</u>	=	=
		k. Radiology	<u>E</u>	<u>E</u>	<u>E</u>	<u>=</u>
		1. Thoracic surgery	<u>E</u>	<u>E</u>	=	=
<u>D.</u>		ical Qualifications				
	<u>1.</u>	General/Trauma Surgeon				
		a. Board certification 10	<u>E</u>	<u>E</u>	<u>E</u>	=
L		b. 16 hours CME/year 11	<u>E</u>	<u>E</u>	=	=
		c. ATLS certification ¹²	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
		d. Multidisciplinary peer review committee attendance > 50% 13	<u>E</u>	<u>E</u>	<u>E</u>	=
	<u>2.</u>	Emergency Medicine ³				
		a. Board certification 10	<u>E</u>	<u>E</u>	Ξ	<u>=</u>
		<u>b.</u> <u>Trauma education – 16 hours CME/year¹¹</u>	<u>E</u>	<u>E</u>	=	
		c. ATLS certification 12	<u>E</u>	<u>E</u>	<u>E</u>	E
		d. Multidisciplinary peer review committee attendance > 50% 13	<u>E</u>	<u>E</u>	<u>E</u>	<u> </u>
	<u>3.</u>	Neurosurgery				_
		a. Board certification	E	<u>E</u>	=	_
		a. Board certification	=		_	
		b. 16 hours CME/year 11	<u>=</u> 	<u>E</u>	<u>-</u>	-

4. Orthopaedic Surgery				
a. Board certification	E	E	=	_
b. 16 hours CME/year in skeletal trauma ¹¹	E	E	=	_
c. Multidisciplinary peer review committee attendance > 50% 13	E	E	E	_
E. Facilities/Resources/Capabilities				
1. Volume Performance 14	<u>E</u>	=	=	_
2. Presence of surgeon at resuscitation (immediately available) ¹⁵	<u>E</u>	<u>E</u>	=	-
3. Presence of surgeon at resuscitation (promptly available) ¹⁶	Ξ	=	<u>E</u>	<u>-</u>
4. Presence of surgeon at operative procedures	<u>E</u>	<u>E</u>	<u>E</u>	E
5. Emergency Department				
a. Personnel				
i. Designated physician director	<u>E</u>	<u>E</u>	<u>E</u>	-
b. Resuscitation Equipment for Patients of All Ages				_
i. Airway control and ventilation equipment	<u>E</u>	<u>E</u>	<u>E</u>	Е
ii. Pulse oximetry	<u>E</u>	<u>E</u>	<u>E</u>	E
iii. Suction devices	<u>E</u>	<u>E</u>	<u>E</u>	E
iv. Electrocardiograph-oscilloscope-defibrillator	<u>E</u>	<u>E</u>	<u>E</u>	E
<u>v.</u> <u>Internal paddles</u>	<u>E</u>	<u>E</u>	<u>E</u>	_
vi. CVP monitoring equipment	<u>E</u>	<u>E</u>	<u>E</u>	_
vii. Standard intravenous fluids and administration sets	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
viii. Large-bore intravenous catheters	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
ix. Sterile Surgical Sets for				
(1) Airway control/cricothyrotomy	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
(2) Thoracostomy	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
(3) Venous cutdown	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
(4) Central line insertion	<u>E</u>	<u>E</u>	<u>E</u>	=
(5) Thoracotomy	<u>E</u>	<u>E</u>	<u>E</u>	=
(6) Peritoneal lavage	<u>E</u>	<u>E</u>	<u>E</u>	=
x. Arterial catheters	<u>E</u>	<u>E</u>	-	<u>=</u>
xi. Drugs necessary for emergency care	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xii. X-ray availability 24 hours/day	<u>E</u>	<u>E</u>	<u>E</u>	<u>=</u>
xiii. Broselow tape	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xiv. Thermal Control Equipment				
(1) For patient	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
(2) For fluids and blood	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xv. Rapid infuser system	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
xvi. Qualitative end-tidal CO ₂ determination	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
c. Communication with EMS vehicles	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
d. Capability to resuscitate, stabilize, and transport pediatric patients 17	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
6. Operating Room				
a. Immediately available 24 hours/day	<u>E</u>	<u>E</u>	Ξ	=
b. Personnel				
<u>i.</u> <u>In-house 24 hours/day ¹⁸</u>	<u>E</u>	Ξ	Ξ	<u> </u>

ii. Available	24 hours/day ¹⁹	=	E	E	_
c. Age-Specific F		_	_	_	=
	nonary bypass	<u>E</u>	=	=	
	microscope	<u>E</u>	<u> </u>	=	=
d. Thermal Contr	<u> </u>		_	_	=
i. For patien		<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
ii. For fluids		<u>E</u>	<u>E</u>	<u>E</u>	E E
	y including C-arm image intensifier	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
f. Endoscopes, br		<u>E</u>	<u>E</u>	<u>E</u>	=
g. Craniotomy ins	*	<u>E</u>	<u>E</u>	=	<u> </u>
	long bone and pelvic fixation	<u>E</u>	<u>E</u>	<u>E</u>	=
i. Rapid infuser s		<u>E</u>	<u>E</u>	<u>E</u>	<u>-</u> E
	overy Room (SICU is acceptable)		=	_=	<u>E</u>
	ses available 24 hours/day	<u>E</u>	<u>E</u>	<u>E</u>	
	monitoring and resuscitation	<u>E</u>	<u>E</u>	<u>E</u>	<u>-</u>
	ssure monitoring equipment	<u>E</u>	<u>E</u>	<u>=</u>	<u>E</u>
<u>i.</u> Pulse oxin	• • •	<u>E</u>	<u>E</u>	<u>E</u>	<u>-</u>
ii. Thermal c	•	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	Care Unit for Injured Patients	브	브	브	<u>E</u>
	ses with trauma training	<u>E</u>	<u>E</u>	<u>E</u>	
	gical director or surgical co-director	<u>E</u>	<u>E</u>	<u>E</u>	=
	ervice physician in-house 24 hours/day ²⁰	<u>E</u>			=
	eted and staffed ICU service ²⁰	<u>E</u>	<u>=</u> <u>E</u>	=	=
	monitoring and resuscitation	<u>E</u>	<u>E</u>	<u>=</u> <u>E</u>	=
	ssure monitoring equipment				=
	• • •	<u>E</u>	<u>E</u>		=
	ry monitoring equipment	<u>E</u>	<u>E</u>	<u>E</u>	<u> </u>
9. Respiratory Therap	use 24 hours/day	Е	Е		
	-	<u>E</u>	<u>E</u>	- -	=
b. On-call 24 hou		=	=	<u>E</u>	=
	es (Available 24 hours/day)	Б	Г		
	ogy technologist	<u>E</u>	<u>E</u>	=	=
b. Angiography		<u>E</u>	<u>E</u>		<u> </u>
c. Sonography	1	<u>E</u>	<u>E</u>	<u>E</u>	=
d. Computed tom		<u>E</u>	<u>E</u>	<u>E</u>	=
	T technician	<u>E</u>	<u>E</u>	=	=
e. Magnetic resor		<u>E</u>	Ξ	=	=
	Service (Available 24 hours/day)	F		-	
a. Standard analy sampling when	ses of blood, urine, and other body fluids, including micro-	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	nd cross-matching	<u>E</u>	<u>E</u>	<u>E</u>	
c. Coagulation str		<u>E</u>	<u>E</u>	<u>E</u>	<u>-</u> E
	e blood bank or access to a community central blood bank	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	orage facilities				=

			1	1	1
	e. Blood gases and pH determinations	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	<u>f.</u> <u>Microbiology</u>	<u>E</u>	<u>E</u>	<u>E</u>	=
	12. Acute Hemodialysis				
	a. <u>In-house</u>	<u>E</u>	=	=	=
	b. <u>Transfer agreement</u>	=	<u>E</u>	<u>E</u>	<u>E</u>
	13. Burn Care—Organized				
	a. <u>In-house or transfer agreement with burn center</u>	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	14. Acute Spinal Cord Management				
	a. <u>In-house or transfer agreement with regional acute spinal cord injury rehabilitation center</u>	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
<u>F.</u>	Rehabilitation Services				
	1. Transfer agreement to an approved rehabilitation facility	<u>E</u>	<u>E</u>	<u>E</u>	<u>E</u>
	2. Physical therapy	<u>E</u>	<u>E</u>	<u>E</u>	_
	3. Occupational therapy	<u>E</u>	<u>E</u>	=	=
	4. Speech therapy	<u>E</u>	<u>E</u>	=	=
	5. <u>Social Services</u>	<u>E</u>	<u>E</u>	<u>E</u>	=
<u>G.</u>	Performance Improvement				
	1. Performance improvement programs	<u>E</u>	<u>E</u>	<u>E</u>	Е
	2. Trauma Registry				
	a. In-house	<u>E</u>	<u>E</u>	<u>E</u>	Е
	b. Participation in state, local, or regional registry	<u>E</u>	<u>E</u>	<u>E</u>	E
	3. Audit of all trauma deaths	<u>E</u>	<u>E</u>	<u>E</u>	E
	4. Morbidity and mortality review	<u>E</u>	<u>E</u>	<u>E</u>	E
	5. Trauma conference – multidisciplinary	<u>E</u>	<u>E</u>	<u>E</u>	_
	6. Medical nursing audit	<u>E</u>	<u>E</u>	<u>E</u>	E
	7. Review of prehospital trauma care	<u>E</u>	<u>E</u>	<u>E</u>	_
	8. Review of times and reasons for trauma-related bypass	<u>E</u>	<u>E</u>	Ξ	_
	9. Review of times and reasons for transfer of injured patients	<u>E</u>	<u>E</u>	<u>E</u>	E
	10. Performance improvement personnel dedicated to care of injured patients	<u>E</u>	<u>E</u>	=	_
Н.	Continuing Education/Outreach				_
	1. Outreach activities ²¹	E	E	=	_
	2. Residency program ²²	<u>E</u>	=	=	_
	3. ATLS provide/participate ²³	E	=	=	_
	4. Programs provided by hospital for:				_
	a. Staff/community physicians (CME)	E	E	E <u>24</u>	_
	b. Nurses	<u>–</u> Е	<u>E</u>	<u>E</u>	_
	c. Allied health personnel	<u> </u>	<u>E</u>	<u>E</u>	_
	d. Prehospital personnel provision/participation	<u>–</u> Е	E	E	
<u>I.</u>	Prevention		_	_	_
	1. Prevention program ²⁵	<u>E</u>	<u>E</u>	=	_
	Collaboration with existing national, regional, state, and community programs ²⁶	<u> </u>	<u>E</u>	<u>E</u>	<u>E</u>
<u>J.</u>	Research Research				
			l	l .	l

Notices of Proposed Rulemaking

1. Research program ²⁷	<u>E</u>	=	Ξ	-
2. Trauma registry performance improvement activities	<u>E</u>	<u>E</u>	<u>E</u>	-11
3. Identifiable Institutional Review Board process	<u>E</u>	=	=	- 1
4. Extramural education presentations	<u>E²⁸</u>	=	=	-
K. Additional Requirements for Trauma Centers Represented as Caring for Pediatric Trauma Patients ²⁹				
1. Trauma surgeons credentialed for pediatric trauma care	<u>E</u>	<u>E</u>	=	-
2. Pediatric emergency department area	<u>E</u>	<u>E</u>	=	=
3. Pediatric resuscitation equipment in all patient care areas	<u>E</u>	<u>E</u>	=	=
4. Microsampling	<u>E</u>	<u>E</u>	<u>E</u>	-
5. Pediatric-specific performance improvement program	Е	E	E	E
5. rediatrie-specific performance improvement program	<u>E</u>	<u> </u>	브	<u>L</u>

⁴ For this criterion, "immediately available" means that:

- 1. For a Level I trauma center, a PGY 4 or 5 surgery resident or a trauma surgeon is on the hospital premises at all times; and
- 2. For all major resuscitations in a Level I, II, or III trauma center:
 - a. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
 - b. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department:
 - For a Level I or II trauma center, no later than 15 minutes after patient arrival; or
 - ii. For a Level III trauma center, no later than 30 minutes after patient arrival.

The minimum threshold for compliance with #2 is 80%.

A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

⁵ For this criterion, "immediately available" means that:

- 1. For a Level I trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is on the hospital premises at all times;
- 2. For a Level II trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department no later than 15 minutes after patient arrival;
- 3. For a Level III trauma center, an anesthesiologist, anesthesiology chief resident, or certified registered nurse anesthetist is present in the emergency department no later than 30 minutes after patient arrival; and
- 4. For a Level I, II, or III trauma center, an anesthesiologist is present for all surgeries.

However, if emergency medicine physicians do not participate in the care of a hospital's trauma patients, an emergency medicine physician is not required to be immediately available 24 hours per day.

1. A physician specialist is present in the emergency department no later than 45 minutes after notification, based on patient need; or

¹ An individual may not serve as trauma medical director for more than one trauma center at the same time.

² For a Level I trauma center, this shall be a full-time position.

³ This does not apply if emergency medicine physicians do not participate in the care of a hospital's trauma patients.

⁶ For this criterion, "immediately available" means that an emergency medicine physician is physically present in the emergency department at all times.

 $[\]frac{7}{2}$ For the criteria in (C)(3)(a)-(1), "promptly available" means that:

Notices of Proposed Rulemaking

2. For hand surgery and microvascular/replant surgery, the owner has transfer agreements to ensure that a patient in need of hand surgery or microvascular/replant surgery can be expeditiously transferred to a health care institution that has a hand surgeon or microvascular/replant surgeon on the premises.

- ⁹ This criterion is satisfied by a dentist or physician authorized by the hospital to perform oral and maxillofacial surgery. If a physician, the individual shall be a plastic surgeon or an otolaryngologist.
- 10 In a Level I or II trauma center, a non-board-certified physician may be included in the trauma service if the physician:
 - 1. If a surgeon, is in the examination process by the American Board of Surgery;
 - 2. If the trauma medical director, is a Fellow of ACS;
 - 3. Unless the trauma medical director, complies with the following:
 - Has a letter written by the trauma director demonstrating that the health care institution's trauma program has a critical need for the physician because of the physician's individual experience or the limited physician resources available in the physician's specialty;
 - b. Has successfully completed an accredited residency training program in the physician's specialty, as certified by a letter from the director of the residency training program;
 - c. Has current ATLS certification as a provider or instructor, as established by documentation;
 - d. Has completed 48 hours of trauma CME within the past three years, as established by documentation;
 - e. Has attended at least 50% of the trauma quality assurance and educational meetings, as established by documentation;
 - Has been a member or attended local, regional, and national trauma organization meetings within the past three
 years, as established by documentation;
 - g. Has a list of patients treated over the past year with accompanying ISS and outcome for each;
 - h. Has a quality assurance assessment by the trauma director showing that the morbidity and mortality results for the physician's patients compare favorably with the morbidity and mortality results for comparable patients treated by other members of the trauma service; and
 - i. Has full and unrestricted privileges in the physician's specialty and in the department with which the physician is affiliated; or
 - 4. Complies with the following:
 - <u>a.</u> Has provided exceptional care of trauma patients, as established by documentation such as a quality assurance assessment by the trauma director;
 - b. Has numerous publications, including publication of excellent research;
 - c. Has made numerous presentations; and
 - d. Has provided excellent teaching, as established by documentation.

In a Level III trauma center, only the trauma medical director is required to be board-certified.

- 11 This criterion applies only to the trauma medical director, the emergency medicine liaison, the neurosurgical trauma liaison, and the orthopaedic trauma liaison. This criterion is satisfied by an average of 16 hours annually, or 48 hours over three years, of verifiable external trauma-related CME. External CME includes programs given by visiting professors or invited speakers and teaching an ATLS course.
- 12 Among the trauma surgeons, only the trauma medical director is required to have current ATLS certification. The other trauma surgeons are required to have held ATLS certification at one time. Among the emergency medicine physicians, only non-board-certified physicians are required to have current ATLS certification. The other emergency medicine physicians are required to have held ATLS certification at one time.
- 13 Among the trauma surgeons, 50% attendance is required for each member of the trauma surgical core group. In the other specialty areas, 50% attendance is required only for the emergency medicine liaison, the neurosurgical trauma liaison, and the orthopaedic trauma liaison.
- 14 Except for Level I trauma centers that care only for pediatric patients, each Level I trauma center shall satisfy one of the following volume performance standards:
 - 1. 1200 trauma admissions per year,
 - 2. 240 admissions with ISS > 15 per year, or

⁸ This criterion is satisfied by a physician authorized by the hospital to perform cardiothoracic surgery.

Notices of Proposed Rulemaking

3. An average of 35 patients with ISS > 15 for the trauma panel surgeons per year.

Burn patients may be included in annual trauma admissions if the trauma service, not a separate burn service, is responsible for burn care in the trauma center.

15 For this criterion, "immediately available" means that for all major resuscitations in a Level I or II trauma center:

- 1. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
- 2. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department no later than 15 minutes after patient arrival.

The minimum threshold for compliance with this criterion is 80%.

A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

16 For this criterion, "promptly available" means that for all major resuscitations in a Level III trauma center:

- 1. If advance notice is provided from the field, a trauma surgeon is present in the emergency department upon patient arrival; and
- 2. If advance notice is not provided from the field, a trauma surgeon is present in the emergency department no later than 30 minutes after patient arrival.

The minimum threshold for compliance with this criterion is 80%.

A PGY 4 or 5 surgery resident may begin resuscitation while awaiting the arrival of the trauma surgeon, but is not a replacement for the trauma surgeon.

- 17 A trauma center that does not admit pediatric patients shall be capable of resuscitating, stabilizing, and transporting pediatric trauma patients.
- 18 A Level I trauma center shall have a complete operating room team in the hospital at all times, so that an injured patient who requires operative care can receive it in the most expeditious manner. The members of the operating room team shall be assigned to the operating room as their primary function; they cannot also be dedicated to other functions within the institution.
- 19 A Level II trauma center shall have a complete operating room team available when needed. The need to have an in-house operating room team depends on a number of things, including the patient population served, the ability to share responsibility for operating room coverage with other hospital staff, prehospital communication, and the size of the community served by the trauma center. If an out-of-house operating room team is used, then this aspect of care shall be monitored by the performance improvement program.
- ²⁰ This requirement may be satisfied by a physician authorized by the hospital to admit patients into the intensive care unit as the attending physician or to perform critical care procedures.
- This requirement is met through having an independent outreach program or participating in a collaborative outreach program. "Collaborative outreach program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating hospitals educate the general public or current or prospective physicians, nurses, prehospital providers, or allied health professionals regarding injury prevention, trauma triage, interfacility transfer of trauma patients, or trauma care.
- 22 A Level I trauma center shall have a functional and documented teaching commitment. This requirement may be met through:
 - 1. A trauma fellowship program; or
 - 2. Active participation with one of the following types of residency programs in emergency medicine, general surgery, orthopaedic surgery, or neurosurgery:
 - a. An independent residency program;
 - b. A regional residency rotation program; or
 - c. A collaborative residency program that includes multiple hospitals, with each non-sponsor participating hospital hosting at least one rotation.

²³ This requirement is met through participating in the provision of ATLS courses and having ATLS instructors on staff.

Notices of Proposed Rulemaking

- 24 When a Level III trauma center is in an area that contains a Level I or Level II trauma center, this is not required.
- 25 This requirement is met through having an independent prevention program or participating in a collaborative prevention program. "Collaborative prevention program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating health care institutions promote injury prevention through primary, secondary, or tertiary prevention strategies. An independent or collaborative prevention program shall include:
 - 1. Conducting injury control studies,
 - 2. Monitoring the progress and effect of the prevention program,
 - 3. Providing information resources for the public, and
 - 4. Each participating hospital's designating a prevention coordinator who serves as the hospital's spokesperson for prevention and injury control activities.
- 26 This requirement is met through participating in a prevention program organized at the national, regional, state, or local community level.
- This requirement is met through having an independent research program or participating in a collaborative research program. "Collaborative research program" means an organized effort, including multiple hospitals or sponsored or coordinated by a Regional Council or the Department, through which participating hospitals systematically investigate issues related to trauma and trauma care.

Injury control studies are considered to be research program activities if they have a stated focused hypothesis or research question.

- 28 The trauma program shall provide at least 12 educational presentations every three years outside the academically affiliated institutions of the trauma center.
- ²⁹ A trauma center is required to comply with the requirements of (K)(1) through (6), in addition to the requirements in (A) through (J), if the trauma center is represented as caring for pediatric trauma patients. "Represented as caring for pediatric trauma patients" means that a trauma center's availability or capability to care for pediatric trauma patients is advertised to the general public, health care providers, or emergency medical services providers through print media, broadcast media, the Internet, or other means such as the EMSystem® administered by the Department.
- 30 The trauma center shall have a PICU available onsite.
- 31 This requirement may be satisfied by a transfer agreement.